MAY - 3 2012 K121006

510(k) Summary	
510(k) Number	
Date Prepared:	April 2, 2012
Submitter Information:	
Manufacturer Name/Address:	St. Jude Medical - Atrial Fibrillation Division One St. Jude Medical Drive St. Paul, MN 55117 Establishment Registration Number: 2184149
Submitter Name/Address:	St. Jude Medical - Atrial Fibrillation Division 14901 DeVeau Place Minnetonka, MN 55345 Establishment Registration Number: 3005188751
Contact Person:	Nicole Marwick Sr. Regulatory Affairs Specialist Tel: 651-756-5162 Fax: 952-930-9481 nmarwick@sjm.com
Device Information:	
Trade Name:	EnSite Array Multi-Electrode Diagnostic Catheter
Common Name:	Electrode Recording Catheter
Classification Name:	Electrode Recording Catheter
Classification:	Class II, 21 CFR 870.1220, Product Code DRF
Predicate Device(s):	EnSite Array Multi-Electrode Diagnostic Catheter (K983456)
Device Description:	The EnSite Array Multi-electrode Diagnostic Catheter (EnSite Array Catheter) is a single use, 9 French, percutaneous catheter. The EnSite Array Catheter is designed for use only with the EnSite System and for deployment in the right atrium. The proximal end contains the patient cable electrical connector, an inflation port for the distal balloon/braid multi-electrode array (MEA), luer port compatible with a 0.035" guidewire, and a push shaft to facilitate expansion and deployment of the MEA. The shaft is a coaxial design with a polyurethane outer sheath. At the distal end in addition to the MEA, there are three ring electrodes; one distal and two proximal mounted at specific locations to the

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	MEA. The tip of the catheter is a pigtail shape to minimize trauma to the endocardium. The EnSite Array Catheter does not require direct contact with the endocardium for the detection of intracardiac electrograms. The EnSite System connected to the EnSite Array Catheter utilizes proprietary software algorithms to reconstruct and display right atrial endocardiograms detected by the EnSite Array Catheters' MEA.
Intended Use/Indications for Use:	The EnSite Array Multi-Electrode Diagnostic Catheter, when used with the EnSite System, is intended to be used in the right atrium of patients with complex arrhythmias that may be difficult to identify using conventional mapping systems alone (i.e. linear mapping catheters).
Comparison to Predicate Devices:	The modified EnSite Array Multi-Electrode Diagnostic Catheter has the same intended use and fundamental scientific technology as the predicate device. All technological characteristics of the modified EnSite Array Multi-Electrode Diagnostic Catheter are substantially equivalent to the predicate device including packaging, biocompatibility, sterilization, and labeling. Through biocompatibility testing and material change evaluation it was demonstrated that the design modifications do not adversely affect the safety and effectiveness.
Summary on Non-Clinical Testing:	An evaluation of the modified EnSite Array Multi-Electrode Diagnostic Catheter was performed to verify the device modifications. It was concluded that the modified EnSite Array Multi-Electrode Diagnostic Catheter design meets the product specification and intended use. Biocompatibility was confirmed in accordance with ISO 10993-1.
Summary of Clinical Testing:	This section is not applicable for this submission. No clinical testing was submitted, referenced or relied upon for a determination of substantial equivalence.
Statement of Equivalence:	The modified St. Jude Medical EnSite Array Multi-Electrode Diagnostic Catheter has the same intended use and technological characteristics as the predicate device. Based on the results of the biocompatibility testing per ISO 10993-1 St. Jude Medical's modified EnSite Array Multi-Electrode Diagnostic Catheter has been shown to be substantially equivalent to the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAY 3 2012

St. Jude Medical
c/o Ms. Nicole Marwick
Senior Regulatory Affairs Specialist
14901 DeVeau Place
Minnetonka, MN 55345

Re: K121006
Trade/Device Name: EnSite Array Multi-Electrode Diagnostic Catheter
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode recording catheter or electrode recording probe
Regulatory Class: Class II (two)
Product Code: MTD
Dated: April 2, 2012
Received: April 3, 2012

Dear Ms. Marwick:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(K) Number (if known): K121006

Device Name: EnSite Array Multi-Electrode Diagnostic Catheter

Indications for Use:

The EnSite Array Multi-Electrode Diagnostic Catheter, when used with the EnSite System, is intended to be used in the right atrium of patients with complex arrhythmias that may be difficult to identify using conventional mapping systems alone (i.e. linear mapping catheters).

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K121006